REMARKS

Claims 1, 6, 8, 11, 12, 16, and 21 have been amended.

Claim 23 was previously cancelled.

Claims 20 and 22 are cancelled.

Claims 1-19, 21, 24, and 25 are currently pending in this application.

Claims 1, 16, and 24 are in independent format.

1. Rejections Under 35 U.S.C. § 102

A. Claims 1, 2, 9-15, 19-22, 24, and 25

Claims 20 and 22 have been cancelled.

The Examiner's rejection of Claims 1, 2, 9-15, 19, 21, 24, and 25 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,866,639 B2 to *Causevic* is respectfully traversed. The Examiner's stated basis for the rejection is that the '639 *Causevic* reference discloses a handheld testing means with a plurality of independently operable modular auditory and non-auditory testing subsystems, including a processor which receives data from the subsystems and generates an index value representative of at least one disorder in a human patient, together with the other limitations set forth in Claims 1, 2, 9-15, 19, 21, 24, and 25.

The MPEP §2131 provides:

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." *Verdegall Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as contained in the ... claim"

Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 9 USQP2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim.

In contrast to the Examiner's stated basis for the rejection, the '639 *Causevic* reference fails to disclose a processor system coupled to a plurality of response testing subsystems which is configured *to generate an index value representative of a disorder* using combined data from *more than one* response testing subsystem. Rather, the '639 *Causevic* reference describes a hand held testing device which includes a processor capable of carrying out one or more tests on a human patient, using various testing systems (i.e., an otoreflectance testing system, an ABR testing system, and a DPOAE testing system) and of displaying the signal results of the *individual tests*. Col. 8, lines 26-34; Col. 10, lines 47-52; Col. 13, lines 1-5 and 51-55; Col. 15, lines 26-30; Col. 16, lines 1-4 and 35-39. There is no disclosure in the '639 *Causevic* reference of a processor configured *to generate an index value representative of a disorder* using *combined data* from *more than one* response testing subsystem.

Accordingly, the '639 *Causevic* reference fails to disclose each and every limitation set forth in Independent Claims 1 and 24, and therefore fails to anticipate these claims under 35 U.S.C. § 102(e).

Dependent Claims 2, 9-15, and 25 each depend either directly or indirectly from independent Claims 1 and 24, and therefore are seen as not anticipated under 35 U.S.C. § 102(e) by the '639 *Causevic* reference for at least the same reasons.

Dependent Claims 19 and 21 each depend either directly or indirectly from independent Claim 16, which is not rejected under 35 U.S.C. § 102(e) by the '639 *Causevic* reference. Since these dependent claims include each and every limitation of

their parent claim, they are seen as not anticipated under 35 U.S.C. § 102(e) by the '639 *Causevic* reference for at least the same reasons as independent Claim 16.

B. Claims 1, 5, 9-15, 24, and 25

The Examiner's rejection of Claims 1, 5, 9-15, 24, and 25 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,589,189 B2 to *Meyerson et al.* is respectfully traversed. The Examiner's stated basis for the rejection is that the '189 *Meyerson et al.* reference discloses a handheld testing means with a plurality of independently operable modular auditory and non-auditory testing subsystems, including a processor which receives data from the subsystems and generates an index value representative of at least one disorder in a human patient, together with the other limitations set forth in Claims 1, 5, 9-15, 24, and 25.

In contrast to the Examiner's stated basis for the rejection, the '189 *Meyerson et al.* reference fails to disclose a processor system coupled to a plurality of response testing subsystems which is configured *to generate an index value representative of a disorder* using combined data from *more than one* response testing subsystem. Rather, the '189 *Meyerson et al.* reference describes a hand held testing device for monitoring intercranial pressure (ICP) which includes a processor capable of carrying out one or more tests on a human patient, using various testing systems (i.e., an otoacoustic emission testing system, a pulse oximeter, a respirator, or a heart monitor) and of displaying the signal results of the *individual tests*. For example, the '189 *Meyerson et al.* reference describes that the OAE response is a relative indicator of ICP. (Col. 9, lines 15-16). Similarly, data received from other testing subsystems (hear rate, cerebral

oxygenation, etc.) may be displayed to be interpreted *in conjunction* with an ICP value. (Col. 10, lines 50-62). Finally, signal data received from different sub-systems may be used to *validate* a response signal. (Col. 10, line 63 – Col. 11, line 48). Validation is a confirmation of the validity of a result, and is not equivalent to utilizing the results from two or more testing subsystems to generate an index value representative of a disorder.

Hence, there is no disclosure in the '189 *Meyerson et al.* reference of a processor configured *to generate an index value representative of a disorder* using *combined data* from *more than one* response testing subsystem. Accordingly, the '189 *Meyerson et al.*reference fails to disclose each and every limitation set forth in Independent Claims 1 and 24, and therefore fails to anticipate these claims under 35 U.S.C. § 102(e). Dependent Claims 2, 9-15, and 25 each depend either directly or indirectly from independent Claims 1 and 24, and therefore are seen as not anticipated under 35 U.S.C. § 102(e) by the '189 *Meyerson et al.* reference for at least the same reasons.

2. Rejections Under 35 U.S.C. § 103

A. Claims 3 and 4

The Examiner's rejection under 35 U.S.C. § 103(a) of Claims 3 and 4 as being unpatentable over U.S. Patent No. 6,866,639 B2 to *Causevic et al.* in view of U.S. Patent No. 6,544,190 B1 to *Smits et al.* is respectfully traversed. The Examiner's stated basis for the rejection is that the '190 *Smits et al.* reference discloses an end-tidal breath analyzer subsystem, and that it would be obvious to modify the device of the

'639 *Causevic et al.* reference to include the ability to analyze breath samples per the teachings of *Smits et al.*

As set forth above, the '639 *Causevic et al*. reference fails to disclose all the required limitations of the parent independent Claim 1, including the requirement of a processor configured *to generate an index value representative of a disorder* using *combined data* from *more than one* response testing subsystem. The '190 *Smits et al*. reference is merely directed towards a single type of testing system (i.e., end-tidal breath analysis) and fails to teach or suggest a system for combining results from multiple testing subsystems to generate a index value representative of a disorder or condition in a human patient. Accordingly, the combination of the '639 *Causevic et al*. reference with the '190 *Smits et al.* reference fails to render Claims 3 and 4 obvious under 35 U.S.C. § 103(a).

B. Claims 2-4

The Examiner's rejection under 35 U.S.C. § 103(a) of Claims 2-4 as being unpatentable over U.S. Patent No. 6,589,189 B2 to *Meyerson et al*. in view of U.S. Patent No. 6,544,190 B1 to *Smits et al*. is respectfully traversed. The Examiner's stated basis for the rejection is that the '190 *Smits et al*. reference discloses an end-tidal breath analyzer subsystem, and that it would be obvious to modify the device of the '189 *Meyerson et al.* reference to include the ability to analyze breath samples per the teachings of *Smits et al.*

As set forth above, the '189 *Meyerson et al.* reference fails to disclose all the required limitations of the parent independent Claim 1, including the requirement of a

processor configured *to generate an index value representative of a disorder* using *combined data* from *more than one* response testing subsystem. The '190 *Smits et al.* reference is merely directed towards a single type of testing system (i.e., end-tidal breath analysis) and fails to teach or suggest a system for combining results from multiple testing subsystems to generate a index value representative of a disorder or condition in a human patient. Accordingly, the combination of the '189 *Meyerson et al.* reference with the '190 *Smits et al.* reference fails to render Claims 2-4 obvious under 35 U.S.C. § 103(a).

C. Claims 5-7 and 16-22

Claims 20 and 22 have been cancelled.

The Examiner's rejection under 35 U.S.C. § 103(a) of Claims 5-7 and 16-22 as being unpatentable over U.S. Patent No. 6,866,639 B2 to *Causevic et al.* in view of U.S. Patent Application Publication No. 2003/0208113 A1 to *Mault et al.* is respectfully traversed

Turning first to Claims 5-7, the Examiner's stated basis for the rejection is that the '113 *Mault et al.* reference discloses a blood analyte monitoring subsystem, and that it would be obvious to modify the device of the '639 *Causevic et al.* reference to include the ability to analyze blood chemical compounds per the teachings of *Mault et al.*

As set forth above, the '639 *Causevic et al.* reference fails to disclose all the required limitations of the parent independent Claim 1, including the requirement of a processor configured *to generate an index value representative of a disorder* using *combined data* from *more than one* response testing subsystem. The '113 *Mault et al.*

reference is merely directed towards a single type of testing system (i.e., blood glucose / glycemic index analysis) and fails to teach or suggest a system for combining results from *multiple* testing subsystems to generate a index value representative of a disorder or condition in a human patient. Accordingly, the combination of the '639 *Causevic et al.* reference with the '113 *Mault et al.* reference fails to render Claims 5-7 obvious under 35 U.S.C. § 103(a).

With respect to the rejection of independent Claim 16 and dependent Claims 17-19 and 21, the Examiner's stated basis for the rejection is that the '113 *Mault et al.* reference discloses a hemolysis monitoring subsystem, and that it would be obvious to modify the device of the '639 *Causevic et al.* reference to include the ability to analyze blood chemical compounds per the teachings of *Mault et al.*

Independent Claim 16 has been amended to include the limitation of a processor coupled to each testing subsystem to operate the subsystems and to *generate an index value representative of the medical disorder responsive to indicators generated by at least two of the testing subsystems*. Essentially, this amendment to Claim 16 merges limitations found in now-cancelled dependent Claims 20 and 22 with the limitations of parent Claim 16.

As set forth above, the '639 *Causevic et al.* reference fails to disclose the requirement of a processor configured *to generate an index value representative of a disorder* using *combined data* from *more than one* response testing subsystem, now found in amended Claim 16. The '113 *Mault et al.* reference is merely directed towards a single type of testing system (i.e., blood glucose / glycemic index analysis) and fails to teach or suggest a system for combining results from *multiple* testing subsystems to

generate a index value representative of a disorder or condition in a human patient. Accordingly, the combination of the '639 *Causevic et al.* reference with the '113 *Mault et al.* reference fails to render amended Claim 16 obvious under 35 U.S.C. § 103(a).

Claims 17-19 and 21 each depend directly form Claim 16, and include the all of the limitations of the Claim. Accordingly, dependent Claims 17-19 and 21 are seen as allowable under 35 U.S.C. § 103(a) over the combination of the '639 *Causevic et al.* reference with the '113 *Mault et al.* reference for at least the same reasons as amended parent Claim 16.

D. Claims 6, 7, and 16-22

Claims 20 and 22 have been cancelled.

The Examiner's rejection under 35 U.S.C. § 103(a) of Claims 6, 7, and 16-22 as being unpatentable over U.S. Patent No. 6,589,189 B2 to *Meyerson et al*. in view of U.S. Patent Application Publication No. 2003/0208113 A1 to *Mault et al*. is respectfully traversed

Turning first to Claims 6 and 7, the Examiner's stated basis for the rejection is that the '113 *Mault et al*. reference discloses a blood analyte monitoring subsystem, and that it would be obvious to modify the device of the '189 *Meyerson et al.* reference to include the ability to analyze blood chemical compounds per the teachings of *Mault et al.*

As set forth above, the '189 *Meyerson et al.* reference fails to disclose all the required limitations of the parent independent Claim 1, including the requirement of a processor configured *to generate an index value representative of a disorder* using

combined data from *more than one* response testing subsystem. The '113 *Mault et al.* reference is merely directed towards a single type of testing system (i.e., blood glucose / glycemic index analysis) and fails to teach or suggest a system for combining results from *multiple* testing subsystems to generate a index value representative of a disorder or condition in a human patient. Accordingly, the combination of the '189 *Meyerson et al.* reference with the '113 *Mault et al.* reference fails to render Claims 6 and 7 obvious under 35 U.S.C. § 103(a).

With respect to the rejection of independent Claim 16 and dependent Claims 17-19 and 21, the Examiner's stated basis for the rejection is that the '113 *Mault et al.* reference discloses a hemolysis monitoring subsystem, and that it would be obvious to modify the device of the '189 *Meyerson et al.* reference to include the ability to analyze blood chemical compounds per the teachings of *Mault et al.*

Independent Claim 16 has been amended to include the limitation of a processor coupled to each testing subsystem to operate the subsystems and to *generate an index value representative of the medical disorder responsive to indicators generated by at least two of the testing subsystems*. Essentially, this amendment to Claim 16 merges limitations found in now-cancelled dependent Claims 20 and 22 with the limitations of parent Claim 16.

As set forth above, the '189 *Meyerson et al.* reference fails to disclose the requirement of a processor configured *to generate an index value representative of a disorder* using *combined data* from *more than one* response testing subsystem, now found in amended Claim 16. The '113 *Mault et al.* reference is merely directed towards a single type of testing system (i.e., blood glucose / glycemic index analysis) and fails to

teach or suggest a system for combining results from ***multiple*** testing subsystems to generate a index value representative of a disorder or condition in a human patient. Accordingly, the combination of the '189 *Meyerson et al.* reference with the '113 *Mault et al.* reference fails to render amended Claim 16 obvious under 35 U.S.C. § 103(a).

Claims 17-19 and 21 each depend directly form Claim 16, and include the all of the limitations of the Claim. Accordingly, dependent Claims 17-19 and 21 are seen as allowable under 35 U.S.C. § 103(a) over the combination of the '189 *Meyerson et al.* reference with the '113 *Mault et al.* reference for at least the same reasons as amended parent Claim 16.

E. Claim 8

The Examiner's rejection under 35 U.S.C. § 103(a) of Claim 8 as being unpatentable over U.S. Patent No. 6,866,639 B2 to *Causevic et al.* in view of U.S. Patent Application Publication No. 2003/0208113 A1 to *Mault et al.*, and further in view of U.S. Patent Application Publication No. 2004/0138539 A1 to *Jay et al.* is respectfully traversed. The Examiner's stated basis for the rejection is that the '113 *Mault et al.* reference discloses a blood analyte monitoring subsystem, but not specifically monitoring chemical compounds associated with lactose malabsorption. The '539 *Jay et al.* reference notes that lactose levels in blood may be monitored, and hence, the Examiner contends that it would be obvious to modify the device of the '639 *Causevic et al.* reference to include the ability to analyze blood chemical compounds per the teachings of *Mault et al.* and specifically for the compounds shown in the '539 *Jay et al.* reference.

As set forth above, the '639 *Causevic et al.* reference fails to disclose all the required limitations of the parent independent Claim 1, including the requirement of a processor configured *to generate an index value representative of a disorder* using *combined data* from *more than one* response testing subsystem. The '113 *Mault et al.* reference is merely directed towards a single type of testing system (i.e., blood glucose / glycemic index analysis) and fails to teach or suggest a system for combining results from *multiple* testing subsystems to generate a index value representative of a disorder or condition in a human patient. Similarly, the '539 *Jay et al.* reference is directed towards a single type of testing system (i.e., a blood species concentration testing system) and fails to teach or suggest a system for combining results from *multiple* testing subsystems to generate a index value representative of a disorder or condition in a human patient. Accordingly, the combination of the '639 *Causevic et al.* reference with both the blood testing system of the '113 *Mault et al.* reference and the specific blood chemical analysis of the '539 *Jay et al.* reference fails to render Claim 8 obvious under 35 U.S.C. § 103(a), as the cited combination clearly lacks one or more limitations of the claim.

F. Claim 8

The Examiner's rejection under 35 U.S.C. § 103(a) of Claim 8 as being unpatentable over U.S. Patent No. 6,589,189 B2 to *Meyerson et al.* in view of U.S. Patent Application Publication No. 2003/0208113 A1 to *Mault et al.*, and further in view of U.S. Patent Application Publication No. 2004/0138539 A1 to *Jay et al.* is respectfully traversed. The Examiner's stated basis for the rejection is that the '113 *Mault et al.*

reference discloses a blood analyte monitoring subsystem, but not specifically monitoring chemical compounds associated with lactose malabsorption. The '539 *Jay et al.* reference notes that lactose levels in blood may be monitored, and hence, the Examiner contends that it would be obvious to modify the device of the '189 *Meyerson et al.* reference to include the ability to analyze blood chemical compounds per the teachings of *Mault et al.* and specifically for the compounds shown in the '539 *Jay et al*. reference.

As set forth above, the '189 *Meyerson et al.* reference fails to disclose all the required limitations of the parent independent Claim 1, including the requirement of a processor configured *to generate an index value representative of a disorder* using *combined data* from *more than one* response testing subsystem. The '113 *Mault et al*. reference is merely directed towards a single type of testing system (i.e., blood glucose / glycemic index analysis) and fails to teach or suggest a system for combining results from *multiple* testing subsystems to generate a index value representative of a disorder or condition in a human patient. Similarly, the '539 *Jay et al*. reference is directed towards a single type of testing system (i.e., a blood species concentration testing system) and fails to teach or suggest a system for combining results from *multiple* testing subsystems to generate a index value representative of a disorder or condition in a human patient. Accordingly, the combination of the '189 *Meyerson et al.* reference with both the blood testing system of the '113 *Mault et al.* reference and the specific blood chemical analysis of the '539 *Jay et al.* reference fails to render Claim 8 obvious under 35 U.S.C. § 103(a), as the cited combination clearly lacks one or more limitations of the claim.

3. Conclusion

If for any reason the Examiner is unable to allow the application on the next Office Action and feels that an interview would be helpful to resolve any issues, the Examiner is respectfully requested to contact the undersigned attorney for the purpose of arranging such an interview.

Respectfully submitted,

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